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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* DOMINIC P. BEHAN and DEREK T. CHALMERS

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Appeal 2011-009250
Application 09/060,188
Technology Center 1600

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Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for lack of utility and enablement. We have jurisdiction under 35 U.S.C. § 6(b).

## STATEMENT OF THE CASE

The following claim is representative and reads as follows:

69. A method for directly identifying a non-endogenous candidate compound as a compound that stimulates an endogenous G protein coupled receptor (GPCR) or reduces the activity of an active receptor state of an endogenous GPCR, wherein an endogenous ligand for said endogenous GPCR has not been identified, said method comprising the steps of:

(a) obtaining a constitutively activated form of said endogenous GPCR, wherein said constitutively activated GPCR comprises a mutation in its amino acid sequence that increases its constitutive activity relative to said endogenous GPCR;

(b) contacting the non-endogenous candidate compound with said constitutively activated GPCR;

(c) analyzing whether said non-endogenous candidate compound is a compound that stimulates said endogenous GPCR or reduces the activity of an active receptor state of said endogenous GPCR, by measuring the ability of the candidate compound to stimulate or inhibit functionality of said constitutively activated GPCR, respectively.

*Cited References*

The Examiner relies on the following prior art references:

Feldman, Ross D., *Deactivation of Vasodilator Responses by GRK2 Overexpression: A Mechanism or the Mechanism for Hypertension*?, 61Mol. Pharmacol 707-709 (2002).

Janigro, Damir, *Gene Expression in Temporal Lobe Epilep*sy, 8 Epilepsy Currents 23-24 (2008).

Liao et al., *STRL33, A Novel Chemokine Receptor-like Protein, Functions as a Fusion Cofactor for Both Macrophage-tropic and T Cell Line-tropic HIV-1*, 185 The Journal of Experimental Medicine 2015-2023 (1997).

Alkhatib, Ghalib et al., *A new SIV co-receptor, STRL33*, 388 NATURE 238 (1997).

Farzan et al., *Two Orphan Seven-Transmembrane Segment Receptors Which Are Expressed in CD4-positive Cells Support Simian Immunodeficiency Virus Infection*, 186 J. Exp. Med. 405-411 (1997).

Press Release 1, Exhibit E, Arena Pharmaceuticals, Inc.

Press Release 2, Exhibit F, file://C:\Documents and Settings\DCS\Desktop\AREN-001CIP draft\Press Releases NBIX.htm (2007).

*Grounds of Rejection*

1. Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. § 101 for lack of utility.

2. Claims 34, 45-52, 61, 62, 69, 77, 79 and 81 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

## FINDINGS OF FACT

The findings of fact are set forth in the Answer at pages 3-8. Highlighted facts follow.

1. An orphan receptor is defined on page 20 of the Specification, as "an endogenous receptor for which the endogenous ligand specific for that receptor has not been identified or is not known." (*See also* Ans. 5.)

2. "The previously submitted references provide evidence of identification of an endogenous, naturally occurring molecule specific for each of STRL33, gpr1, and gpr15. Farzan et al (1998; Exhibit B) teaches that "The gp120 [viral] glycoprotein binds the CD4 molecule, following which the gp120- CD4 complex binds one of the members of the chemokine receptor subgroup of seven transmembrane segment (7-TMS) receptor" (pg 405). Farzan et al further identifies the7-TMS receptors gpr1 and gpr15 as "coreceptors for SIV [simian immunodeficiency virus]". Thus, Farzan et al teach that the gp120-CD4 complex binds to each of gpr1 and gpr15. Farzan et al do not teach whether or not the CD4 portion of the complex binds directly to

> gpr1 or gpr15, but the term "specific" encompasses either direct or indirect binding through a second molecule (i.e., the gp120-CD4 complex "specifically" binds to gpr1 or gpr15 as opposed to binding to most other cell surface molecules). The CD4 component of this complex is a material which a mammal naturally produces, and thus meets the definition of endogenous in the instant specification. Thus, Farzan et al teach an endogenous, naturally occurring molecule (CD4) specific for gpr1 and gpr15. Thus, gpr1 and gpr15 are not receptors as defined by the instant claims."

(Ans. 13-14.)

3. "Similarly, Liao et al (1997; Exhibit B) teaches that STRL33 is a cofactor for HIV entry in cells expressing CD4; thus CD4 is an endogenous ligand for STRL33. Thus, at the time of filing of the instant application neither of STRL33, gpr1 or gpr15 was a receptor as encompassed by the instant claims." (Ans. 14.)

*Discussion*

ISSUE

The Examiner concludes that

> [t]he specification does not disclose a patentable utility for the 'non-endogenous candidate compound' that stimulates or reduces the activity of an orphan GPCR that is identified by the claimed screening method, and therefore the claimed method lacks patentable utility. The claimed methods lack specific and substantial utility because there is no specific and substantial utility for a non-endogenous modulatory compound identified by the claimed methods. Each orphan GPCR described in the specification for use with the claimed method lacks a specific and substantial utility….The specification does not provide a reasonable correlation between the activity of any of the orphan GPCR's and a specific and substantial use (e.g., treatment of a disease associated with the activity of the GPCR).

(Ans. 7.)

Appellants contend that "'[t]he method of this invention solves a major problem of finding pharmacologically effective compounds for regulation of receptor activity even in the absence of any prior knowledge about the endogenous ligand to the receptor.'" (App. Br. 7.) Appellants further argue that "it is possible to know a receptor's function and develop and market pharmaceutical agents targeting it without any understanding of the natural ligand which activates it" (*id.* at. 8) for example the opioid receptor. Appellants argue that the Appendix evidence shows that orphan GPCR receptors possess utility. (*See id.* at 9.)

The issue is: Does the claimed invention possess utility? Is the claimed invention enabled?

## PRINCIPLES OF LAW

Section 101 requires a utility that is both substantial and specific. A substantial utility requires "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). A specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

"It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101." *Fisher* at 1378.

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'). "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366.

## ANALYSIS

We agree with the Examiner's fact finding, statement of the rejection and responses to Appellants' arguments as set forth in the Answer and find the Examiner has set forth a prima facie case of lack of utility and enablement. We provide the following additional comment. We agree with the Examiner that the disclosure and evidence of record does not provide the claimed methods with specific and substantial utility because there is no specific and substantial utility for a non-endogenous modulatory compound identified by the claimed methods.

Appellants rely on several publications in the Evidence Appendix to the Appeal Brief in support of patentability and utility. In particular, Appellants argue that Liao and Alkhatib "disclose a human orphan GPCR associated with the infectivity and pathology of the virus that causes AIDS."

(App. Br. 9.) Appellants argue that Farzan discloses orphan receptor gpr1 and gpr15 are cofactors for retroviral entry into cells. (*See id.* at 10.)

However, as indicated by the Examiner (FF2, 3) the receptors of Liao, Alkhatib and Farzan are not orphan receptors within the scope of the claims because their function is known.

Thus, for the reasons of record, the Specification does not demonstrate a useful function for an orphan GPCR encompassed by the claims. The Specification does not teach any specific and substantial pharmaceutical use for an agent that modulates a receptor in absence of the knowledge of its natural ligand. "[T]he identification of such 'pharmaceutical' use represents 'further research' that must be completed in order for the invention to prove useful at some future date." (Ans. 11.)

The utility and enablement rejections are affirmed.

## CONCLUSION OF LAW

The claimed invention does not possess utility and is not enabled by the disclosure.

## TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

## AFFIRMED

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